

REMARKS

Claims 1-3, 21, 22, 24 and 27 remain in this application. Claim 1 has been cancelled. Claim 24 has been amended. Claims 2, 21 and 22 have been amended to depend upon claim 3. Claim 27 has been amended to depend upon claim 24. Applicants respectfully request reconsideration in view of the above amendments and the following remarks.

Discussion of the Personal Interview

Applicants' representatives, Daniel A. Scola, Jr. and Nichole Martiak, wish to thank Examiner Patterson for granting them a personal interview on September 10, 2007, to discuss the subject application. Applicants appreciate the Examiner's statement that the arguments presented in the interview in regards to the non fibrillar structure of claim 3 appear to overcome the prior art. These arguments follow.

Applicants' Response to 35 U.S.C. §103 Rejection over Landi in view of Nagasawa

Claims 1, 3 and 22 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 5,141,522 to Landi et al. (hereinafter "Landi") in view of U.S. Patent No. 5,723,526 to Nagasawa (hereinafter "Nagasawa"). Claim 1 has been canceled. Applicants respectfully traverse the rejection on the grounds that the combination of Landi and Nagasawa fails to teach or suggest Applicants' claims 3 and 22, and thus, fails to make out a *prima facie* case of obviousness.

In this rejection, the Examiner acknowledges that Landi fails to disclose an interpenetrating polymer network, but alleges that:

Nagasawa teaches PTFE that is an interpenetrating polymer network for use in the making of a device for the purpose of obtaining a device that is superior in impact resistance. One of ordinary skill in the art would have therefore recognized the advantage of providing for the PTFE of Nagasawa in Landi, which comprises a device, depending on the desired impact resistance of the end product. It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made

to have provided for an interpenetrating polymer network in Landi in order to obtain a device that is superior in impact resistance as taught by Nagasawa.

(Office Action of 11/15/2006, at page 5) (citations omitted).

The Examiner's assertions are respectfully traversed. Claim 3 relates to a vascular graft that includes "an interpenetrating polymer network comprising a non-expanded PTFE matrix having no node and fibril structure". Applicants respectfully submit that the combination of Landi and Nagasawa is improper and does not arrive at the presently claimed invention.

Applicant agrees with the Examiner's assessment that Landi does not disclose an IPN. Landi is directed to a composite material used for repairing mammalian tissue and relates to an expanded PTFE having a fibrillar structure. Thus, Landi is concerned with an entirely different problem from the present invention. The composite of Landi contains two biocompatible polymers. The first polymer is non-absorbable, unsintered PTFE, which is used in the composite as a reinforcing binder. The second polymer is a bioabsorbable polymer, which enhances tissue growth.

In addition, Landi only discloses expanded PTFE having a fibrillar structure, which is in contrast to the non-fibrillar PTFE of the present invention. A fibrillar PTFE structure is conventionally associated with a node and fibril structure that is formed by stretching PTFE. This is well known in the art. See for example U.S. Patent No. 5,098,779 to Kranzler, which discloses that "[p]orous PTFE has been available for some time in a form known as expanded PTFE...Expanded PTFE has a microstructure characterized by nodes interconnected by fibrils." (Kranzler, col. 1, ll. 57-62) Expanded PTFE is conventionally formed by taking an extruded tube or sheet of PTFE and stretching it to form a node and fibril structure to create a porous structure that may be used for implantation in the body. It is well known that porous PTFE has distinct advantages over non-expanded PTFE, because the former permits ingrowth by the body and better assimilation and acceptance long term (patency) as an implant. This is extremely important in cases where the implant is a blood vessel.

Although Landi is silent on certain details of his PTFE, his description of the PTFE being fibrillar clearly indicates to one skilled in the art that the material has been expanded to create a node and fibril structure. An article published in *Archives of Surgery* evidences this, explaining that expanded, fibrillated PTFE structures are "characterized by nodes of solid PTFE interconnected by many fine PTFE fibrils. The fibrils are very thin and flexible, and fibroblastic tissue can push them aside, (unless the fibril lengths are too short), allowing complete tissue ingrowth into the total available open space." (Florian et al., *Archives of Surgery*, March 1976, pp. 267-270). The spaces between the nodes and fibrils allow the porous, fibrillated PTFE to assimilate well into the body. Thus, expanded (or fibrillated) PTFE is commonly used as an implant material. In the absence of any other details, reference to PTFE being porous and having fibrils is indicative of an expansion process that creates the node and fibril structure. Therefore, one of ordinary skill in the art reading Landi would understand his description of fibrillar PTFE to mean an expanded PTFE that must therefore possess a node and fibril structure.

Applicants' claim 3 specifically recites that the non-expanded PTFE has "no node and fibril structure." Rather than use the traditional process of expanding the PTFE to create pores by the formation of a node and fibril structure, the present invention creates pores in a non-expanded PTFE by first creating an IPN which contains a polymer that can be removed, and then removing the polymer to leave behind pores in the PTFE. This is distinctly different from Landi. Nowhere in Landi is it disclosed, taught or suggested to use an IPN comprising PTFE having no node and fibril structure. Applicants' claim 3 requires an IPN of non-expanded PTFE having no node and fibril structure and another extractable polymer. Accordingly, Landi on its own lacks any teaching or suggestion of an IPN as recited in Claim 3, nor the use of non-expanded PTFE in creating such an IPN. In fact, Landi suggests the opposite, i.e. no IPN and a PTFE that the ordinary person skilled in the art would understand to have a node and fibril structure because it is fibrillated. Thus, Landi on its own fails to render claim 3 *prima facie* obvious.

The Examiner cites Nagasawa for its teachings of polymers that "interpenetrate each other". (Nagasawa, col. 5, ll. 11-12) However, as Applicant explained at the interview, there is no motivation or suggestion to combine Landi with the teachings of Nagasawa. In fact, there are several reasons why Nagasawa would direct one of reasonable skill in the art away from combining it with Landi in creating a material as recited in Applicant's claims.

First, the specification of Nagasawa explicitly states "a polytetrafluoroethylene is used as the component (d). A polytetrafluoroethylene having a fibril formability is suitable...polytetrafluoroethylene having no fibril formability is unsuitable as the component (d)." (Nagasawa, col. 4, ll. 52-56). As previously discussed, the presence of fibrils in PTFE indicates it has a node and fiber structure as a result of expansion. Thus, Nagasawa teaches against using his "interpenetrating polymers" in PTFE which is unexpanded, i.e., PTFE having no node and fibril structure. As such, Nagasawa actually teaches away from using a non-expanded PTFE matrix having no node and fibril structure. In fact, PTFE having no fibril formability would destroy the intent and purpose of Nagasawa's invention.

Second, Nagasawa expressly teaches that his "interpenetrating polymers" cannot be separated using common organic solvents. Nagasawa states:

The composite rubber used as the component (f) in the present invention has a structure in which the crosslinked networks of the two rubber compositions interpenetrate each other. **It is therefore impossible to separate or extract the two rubber components from each other with an ordinary organic solvent such as acetone, toluene or the like.**
(Nagasawa, at col. 5, ll. 9-13) (emphasis added).

This is a clear statement that the interpenetrating polymers are not easily separated. In fact, given Nagasawa's purpose in making high impact, flame retardant, highly moldable and stiff articles from his polymers, separating any of his polymers from each other is contrary to his purpose and clearly not intended. (Nagasawa, col. 2-3, ll.63-3). Thus, any motivation to

combine Nagasawa with Landi for the purpose of fulfilling Landi's lack of IPN is absent. The combination is clearly not suggested to one of ordinary skill in the art.

In contrast, the present invention uses organic solvents to extract the extractable polymer. (See Table 1). Some of Applicants' useful solvents are expressly stated as being not useful for the purpose of extracting the polymers in Nagasawa's interpenetrating polymers. As such, one of ordinary skill in the art would not find Nagasawa useful in combination with Landi to arrive at the presently claimed invention and in fact, would find Nagasawa directing away from the present invention.

Nagasawa not only fails to provide for, but even teaches away from an IPN comprising a non-expanded PTFE having no node and fibril structure. As such, Nagasawa fails to cure the deficiencies of Landi. Accordingly, the combination of Landi and Nagasawa, fails to render claim 3 *prima facie* obvious.

Applicants respectfully submit that claims 3, and any claims with depend therefrom, are patentable over Landi and Nagasawa, each taken alone or in combination. Reconsideration and withdrawal of the Section 103 rejection based on this combination is respectfully requested.

Applicants' Response to 35 U.S.C. §103 Rejection over Chau

Claim 24 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 4,874,568 to Chau et al. (hereinafter "Chau"). Applicant respectfully request reconsideration based on the above amendment. In particular, Applicants respectfully assert that Chau have amended claim 24 to include an interpenetrating polymer network.

Chau discloses a process for preparing porous membranes to be used in ultrafiltration, distillation and substrates for composite membranes. The pores the Examiner references are created by: coextruding a plurality of layers of two different polymeric materials to form a laminate product; pulverizing the laminate product and recoextruding the pulverized product;

pulverizing the recoextruded material and forming a melt composition into a thin, solid material; contacting the solid material with an extraction medium, whereby soluble materials are removed to leave a porous material; and then separating the extraction medium from the porous material. (Chau; claim 1). The layers of polymeric materials used in Chau are selected from two film-forming polymers.

The Examiner alleges that one of ordinary skill in the art would have utilized the teachings of Chau to modify the pore size in order to have pores that permit tissue ingrowth, the Applicants respectfully submit that such an assertion is incorrect. Not only does Chau disclose a wholly different material than that of the present invention, the pores sizes discussed in Chau are “determined by the thickness of layers or the number of passes through the coextrusion process rather than the extent of mixing, compounding or stretching.” Furthermore, Chau is directed towards membranes that are “characterized by a homogeneous microporous structure with a small pore size, narrow pore size distribution and a sharp size or molecular weight cutoff.” For example, the pores of Example 1 were “0.642 microns to about 0.09 microns with a mean pore size of 0.307 microns”. Even the largest mean pore size as described in Example 4 only had “a mean pore size of about 2.2 to 2.8 microns”. Blood cells are typically approximately 6-8 microns in diameter. Their ability to pass through the pores of the present invention is critical to the tissue ingrowth process. Therefore one of ordinary skill in the art would not look to Chau’s small pore size and narrow pore size distribution to create a PTFE extrudate as described in claim 24 for implantation in the body with any expectation of success.

Furthermore, Chau fails to disclose, teach or suggest a non-expanded PTFE resin having no node and fibril structure. The Examiner however, has alleged that Chau’s inclusion of fluorocarbon in the list of film forming thermoplastic polymeric materials necessarily includes PTFE and further alleges that Chau does not disclose “a node and fibril structure or an expanded PTFE, and therefore discloses a non-expanded PTFE having no node or fibril structure.” (Office Action of 11/15/2006, at page 4). Although there is no mention of expanding the polymers in Chau, it is stated that the film is “stretched to develop the desired void structure”. Further to the

arguments stated above, it is well known to those skilled in the art of PTFE that stretching is synonymous to expansion and therefore Chau teaches use of an expanded PTFE.

Applicants respectfully submit that claim 24 is patentable over Chau. Reconsideration and withdrawal of the Section 103 rejection is respectfully requested.

Applicants' Response to 35 U.S.C. §103 Rejection over Landi in view of Trescony

Claim 21 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Landi in view of U.S. Patent No. 5,607,464 to Trescony (hereinafter "Trescony"). Claim 21 has been amended to depend upon claim 3. Applicants respectfully request reconsideration on the basis that the cited combination fails to teach or suggest Applicants' claims as amended herein.

As stated in detail above, Landi relates to an expanded PTFE having a fibrillar structure. Nowhere in Landi is an IPN comprising a non-expanded PTFE matrix having no node and fibril structure disclosed, taught or suggested. Trescony does not disclose, teach or suggest an IPN of a non-expanded PTFE resin and a solid particulate incompatible with the PTFE and was merely cited for its disclosure of silicone and fails to cure the deficiencies of Landi in this regard. Accordingly, the combination of Landi and Trescony fails to render claims 21 *prima facie* obvious.

Applicants respectfully submit that claim 21 is patentable over Landi and Trescony, each taken alone or in combination. Reconsideration and withdrawal of the Section 103 rejection based on this combination is respectfully requested.

Applicants' Response to 35 U.S.C. §103 Rejection over Chau in view of Trescony

Claim 27 has been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Chau in view of Trescony. Claim 27 depends upon claim 24. As stated in detail above, claim 24 was amended to include an interpenetrating polymer network. Applicants respectfully request reconsideration on the basis that the combination of references fails to teach or suggest

Applicants' claim 27 as amended herein.

As discussed in detail above, Chau relates to a process for preparing porous membranes to be used in ultrafiltration, distillation and substrates for composite membranes. Nowhere in Chau is a PTFE extrudate having an interpenetrating polymer network of a non-expanded PTFE resin and a solid particulate polymeric compound that is incompatible with PTFE disclosed, taught or suggested. Moreover, there is no motivation or suggestion to combine Chau with the teachings of Trescony. Chau fails to disclose, teach or suggest a non-expanded PTFE resin having no node and fibril structure. Trescony does not disclose, teach or suggest an IPN of a non-expanded PTFE resin and a solid particulate incompatible with the PTFE and was merely cited for its disclosure of a polymer comprising silicone. Therefore Trescony fails to cure the deficiencies of Chau in this regard. Accordingly, the combination of Chau and Trescony fails to render claims 27 *prima facie* obvious.

Applicants respectfully submit that claim 27 is patentable over Chau and Trescony, each taken alone or in combination. Reconsideration and withdrawal of the Section 103 rejection based on this combination is respectfully requested.

Applicants' Response to 35 U.S.C. §103 Rejection over Landi in view of Nagasawa and further in view of Chuter

Claim 2 has been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Landi in view of Nagasawa and further in view of U.S. Patent No. 6,293,969 to Chuter (hereinafter "Chuter"). Claim 2 has been amended to depend upon claim 3. Applicants respectfully request reconsideration on the basis that the combination of references fails to teach or suggest Applicants' claim 2, as amended herein.

As discussed in detail above, neither Landi nor Nagasawa discloses, teaches or suggests an IPN comprising a non-expanded PTFE matrix having no node and fibril structure. Chuter was merely cited for its disclosure of a porous PTFE comprised in first and second stents. No where

Application No: 10/002,521
Amendment and Response dated September 16, 2007
Reply to Office Action of May 16, 2007
Docket No: 760-35 CIP/RCE IV
Page 14

in Chuter is an IPN that includes a non-expanded PTFE matrix having no node and fibril structure disclosed, taught or suggested. Therefore, Chuter fails to cure the deficiencies of Landi and Nagasawa in this regard. Accordingly, the combination of Landi, Nagasawa and Chuter fails to render claim 2 *prima facie* obvious.

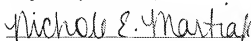
Applicants respectfully submit that claim 2 is patentable over Landi, Nagasawa and Chuter, each taken alone or in combination. Reconsideration and withdrawal of the Section 103 rejection based on this combination is respectfully requested.

Having responded in full to the present Office Action, it is respectfully submitted that the application is in condition for allowance. Favorable action thereon is respectfully solicited.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

Respectfully submitted,



Nichole E. Martiak

Registration No.: 55,832

Attorney for Applicants

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700